

REMARKS/ARGUMENTS

Claims Rejections Under 35 USC §103

Claims 1, 8, 14, 18, 31, 47 and 51 are rejected under 35 USC §103 for reasons previously set forth in the paper mailed from the Office on October 26, 2006, Section 4, page 2 - 5.

Applicant traverses the continuing rejection of the claims because a further review of the US patent # 4,598,089 anti-lipase therapeutic has revealed the following:

The art of U.S. Patent # 4,598,089 recites the oral administration of leucine derivative, commercially known as Orlistat/Lipstatin or Tetrahydrolipstatin, for the prevention and treatment of obesity by the inhibition of lipase activity. This compound is commercially produced by Roche. Other patents and peer review articles have suggested the use of the same compound to improve plasma lipid profile (decrease cholesterol). Other patents have suggested protecting this compound to decrease its side effects i.e. steatorrhea, gastric problems.

From the New Drug Application (NDA 20-766/S-018) by Roche and its commercial clinical patient information flyer (h:\20766ptlbl.doc) reads the following: "Orlistat is an oral prescription weight loss medication used to help obese people to lose weight and keep this weight off. This product should be used together with a reduced-calorie diet that should contain no more than 30% calories from fat. At a dose of 120 mg three times a day, orlistat inhibits dietary fat absorption by approximately 30%".

Let's assume the following:

A standard daily intake of 2000 calories, 30% of calories supplied from fat, 60% from carbohydrates and 10% from protein (from FDA Daily Values).

Nutrient	% Calories¹	Total Calories²	Grams Food³
Fat	30	600	65
Carbohydrates	60	1200	300
Protein	10	200	50
Total	100	2000	415

¹Percentage of calories supplied by each nutrient.

²Net calories supplied by each nutrient from a 2000 cal diet.

³one gram fat=9 calories, gram carbohydrate=4 cal, gram protein=4 cal.

From the table above we can see that fat supplies 600 calories, if Orlistat inhibits 30% of fat then 180 calories (600 x 30%) will not be absorbed. If 1 gram of fat can supplied 9 calories then the amount of extra fat that someone can eat without gaining any weight will be 20 grams (180 / 9). Then the new total intake will be 435 gr or 4.8% more feed ((435/415*100)-100).

Nutrient	% Calories¹	Total Calories²	Grams Food³	Grams Food after Orlistat
Fat	30	600	65	85
Carbohydrates	60	1200	300	300
Protein	10	200	50	50
Total	100	2000	415	435

¹Percentage of calories supplied by each nutrient.

²Net calories supplied by each nutrient form a 2000 kcal diet.

³gram fat=9 cal, gram carbohydrate=4 cal, gram protein=4 cal.

In summary, a normal person consuming 2000 cal/day and taking orlistat three time a day can eat 20 more grams of fat.

However, when compared with the instantly claimed invention it becomes quite clear that the instant invention is surprisingly superior to the invention of the primary reference recited in the instant rejection.

A control subject needs 2000 cal/day or 415 gr food/day to maintain body weight. The instant invention has demonstrated that a mammal taking the compound of the present invention can eat 35.5% more food than the control and maintain comparable weight as the control (Example 5, from table on Page 9 of application), or if translated into a human subject, it would be expected that the human subject could eat 147.3 gr ($415\text{gr} \times 35.5\%$) more food a day and have comparable weight to the control subjects.

It is clear that the instant application is not obvious over US Patent # 4,598,089 or US Patent # 4,598,089 in combination with the secondary references (Ohkaru (Clin, Chim. Acta 182:295-300), JP 02150294, US Patent # 5,585,098 and U.S. Patent # 5,080,895). Applicant therefore requests withdrawal of the instant grounds or rejection.

New Grounds of Rejection

Claims Rejections Under 35 USC §112

Claims 1, 8, 14, 47-49 are rejected under 35 USC §112 ; claims have been amended or withdrawn or cancelled to avoid rejection.

Applicant submit that the case is now in condition for allowance.

Respectfully submitted,



Julio L Pimentel, Ph.D
G.V.D. Corp
3206 Windgate Dr
Buford, GA 30519-1941
770-598-5518
770-945-9762 fax
JLPimen@aol.com